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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,873	11/28/2005	Nikolai Soren Kirkby	P68228US1	7765

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
10/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,873	KIRKBY ET AL.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-27 and 29-37* is/are pending in the application.

4a) Of the above claim(s) *11,12,14,15,29-31 and 35-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10,13,16-27 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/21/06, 10/30/06, 1/3/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-10, 13, 16-27 and 32-34, in the reply filed on February 7, 2008 is acknowledged.

Claims 1, 2, 4-27 and 29-37 are pending. Claims 11, 12, 14, 15, 29-31 and 35-37 have been withdrawn from further consideration as being drawn to non-elected inventions. Claims 3 and 28 have been canceled. Claims 1, 2, 4-10, 13, 16-27 and 32-34 are currently under examination.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on March 21, 2006, October 30, 2006 and January 3, 2007 are in compliance with the provisions of 37 CFR 1.97 and has been considered. An initialed copy is attached hereto.

Claim Rejections - 35 USC § 112

3. Claims 1, 2, 4-10, 13, 16-27 and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the terms "genetic determinant". It is unclear what is meant by said terms, as it is not explicitly defined in the specification. What constitutes a "genetic determinant"? Is said "genetic determinant" a nucleic acid, a protein or some other molecule? As written, it is

impossible to determine the metes and bounds of the claimed invention.

Claim 1 is rendered vague and indefinite by the use of the terms "electrostatic interaction". It is unclear what is meant by said terms, as it is not explicitly defined in the specification. What constitutes an "interaction"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 1 is rendered vague and indefinite by the use of the terms "hydrophobic interaction". It is unclear what is meant by said terms, as it is not explicitly defined in the specification. What constitutes a "hydrophobic interaction"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 1 is rendered vague and indefinite by the use of the terms "contacting group". It is unclear what is meant by said terms, as it is not explicitly defined in the specification. What constitutes a "contacting group"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 17 is rendered vague and indefinite by the use of the phrase "immunogen and/or immunogen delivery system is separated from each other". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. It is unclear whether separate refers to being placed in separate packages or if separate refers to the immunogen being in a separate layer? Moreover, it is unclear how a single entity can be separated from itself. As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim18 is rendered vague and indefinite by the use of the term "enhancer" for transdermal drug delivery. It is unclear what is meant by said term, as it is not explicitly

defined in the specification. What constitutes an "enhancement of transdermal drug delivery"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 24 is rendered vague and indefinite by the use of the phrase "immunological response may act upon subsequent exposure". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. What constitutes an "immunological response that may act upon subsequent exposure"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 5, 9, 10, 13, 16-27, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Foldvari et al. (WO 99/11247).

The rejected claims are drawn to a construct for transdermal delivery of at least one immunogen to an individual comprising:

a) said at least one immunogen;

b) an occlusion vehicle and

c) an immunogen delivery system;

wherein the immunogen delivery system is a complex comprising: i) at least one first sterol and/or at least one second sterol, wherein the at least one second sterol is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and wherein the at least one first sterol and/or the at least one second sterol is capable of forming a complex with at least one first saponin and/or at least one second saponin, and ii) at least one first saponin and/or at least one second saponin, wherein the at least one second saponin is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and wherein the at least one first saponin and/or the at least one second saponin is capable of forming a complex with at least one first sterol and/or at least one second sterol, and optionally iii) at least one contacting group for contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, with the proviso that the at least one contacting group is present when no second sterol is present in the complex and further optionally iv) at least one lipophilic moiety.

Foldvari et al. disclose a biphasic lipid vesicle composition for transdermal administration. The transdermal device comprises a reservoir adapted to retain during storage and release in operation lipid vesicles containing an entrapped immunogen (see page 12, lines 18 and 19). The transdermal device includes a reservoir with a backing layer and membrane joined by an adhesive (see page 12, lines 22-25). Foldvari et al. disclose that the backing layer serves as a protective, impermeable covering to prevent loss of contents. Suitable backing materials include films for medical use (see page 12,

lines 31-33). Foldvari et al. disclose that the device can be applied directly to the skin (see page 12, line 14). Foldvari et al. disclose that the reservoir includes lipid vesicles in suspension, and the lipid vesicles cross the membrane to contact and penetrate the skin for administration of the entrapped immunogen (see page 14, lines 13-15). Also, Foldvari et al. disclose that the membrane is designed to be a rate controlling membrane (see page 14, line 24).

Moreover, in addition to the vesicle-forming lipid component, the invention can include other lipid components capable of being incorporated into lipid bilayers, which for example can include sterols and saponin (see page 8, lines 17-19 and 21; page 12, line 6). Foldvari et al. disclose that the adhesive layer that sticks to the skin is made from a pharmaceutically acceptable pressure sensitive adhesive (see page 13, lines 12-14). Foldvari et al. disclose that a wide variety of immunogens are suitable for use in the present invention, which include but are not limited to antigens derived from microorganisms, such as a virus, bacteria, parasite and/or fungus (see page 6, lines 27-33 and page 7, lines 1-20). Lastly, Foldvari et al. discloses that the biphasic lipid vesicles of the invention include in the central core compartment of the lipid vesicle and in the aqueous space separating the lipid bilayers, an oil-in-water emulsion (see page 7, lines 23-25).

The product of the Foldvari et al. are the same as the instantly claimed invention, the product of Foldvari et al. necessarily i) at least one first sterol and/or at least one second sterol, wherein the at least one second sterol is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic

interaction and a hydrophobic interaction, and wherein the at least one first sterol and/or the at least one second sterol is capable of forming a complex with at least one first saponin and/or at least one second saponin, and ii) at least one first saponin and/or at least one second saponin, wherein the at least one second saponin is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and wherein the at least one first saponin and/or the at least one second saponin is capable of forming a complex with at least one first sterol and/or at least one second sterol, and optionally iii) at least one contacting group for contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, with the proviso that the at least one contacting group is present when no second sterol is present in the complex.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 4-6, 9, 10, 13, 16-27, 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foldvari et al. (WO 99/11247) and British Pharmacopoeia 1993 (Surgical Materials, 1996; 1943-1944).

The rejected claims are drawn to a Construct for transdermal delivery of at least one immunogen to an individual comprising:

a) said at least one immunogen;

b) an occlusion vehicle and

c) an immunogen delivery system;

wherein the immunogen delivery system is a complex comprising: i) at least one first sterol and/or at least one second sterol, wherein the at least one second sterol is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and wherein the at least one first sterol and/or the at least one second sterol is capable of forming a complex with at least one first saponin and/or at least one second saponin, and ii) at least one first saponin and/or at least one second saponin, wherein the at least one second saponin is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and wherein the at least one first saponin and/or the at least one second saponin is capable of forming a complex with at least one first sterol and/or at least one second sterol, and optionally iii) at least one contacting group for contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, with the proviso

that the at least one contacting group is present when no second sterol is present in the complex and further optionally iv) at least one lipophilic moiety.

Foldvari et al. disclose a biphasic lipid vesicle composition for transdermal administration. The transdermal device comprises a reservoir adapted to retain during storage and release in operation lipid vesicles containing an entrapped immunogen (see page 12, lines 18 and 19). The transdermal device includes a reservoir with a backing layer and membrane joined by an adhesive (see page 12, lines 22-25). Foldvari et al. disclose that the backing layer serves as a protective, impermeable covering to prevent loss of contents. Suitable backing materials include films for medical use (see page 12, lines 31-33). Foldvari et al. disclose that the device can be applied directly to the skin (see page 12, line 14). Foldvari et al. disclose that the reservoir includes lipid vesicles in suspension, and the lipid vesicles cross the membrane to contact and penetrate the skin for administration of the entrapped immunogen (see page 14, lines 13-15). Also, Foldvari et al. disclose that the membrane is designed to be a rate controlling membrane (see page 14, line 24).

Moreover, in addition to the vesicle-forming lipid component, the invention can include other lipid components capable of being incorporated into lipid bilayers, which for example can include sterols and saponin (see page 8, lines 17-19 and 21; page 12, line 6). Foldvari et al. disclose that the adhesive layer that sticks to the skin is made from a pharmaceutically acceptable pressure sensitive adhesive (see page 13, lines 12-14). Foldvari et al. disclose that a wide variety of immunogens are suitable for use in the present invention, which include but are not limited to antigens derived from

microorganisms, such as a virus, bacteria, parasite and/or fungus (see page 6, lines 27-33 and page 7, lines 1-20). Lastly, Foldvari et al. discloses that the biphasic lipid vesicles of the invention include in the central core compartment of the lipid vesicle and in the aqueous space separating the lipid bilayers, an oil-in-water emulsion (see page 7, lines 23-25).

The product of the Foldvari et al. are the same as the instantly claimed invention, the product of Foldvari et al. necessarily i) at least one first sterol and/or at least one second sterol, wherein the at least one second sterol is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and wherein the at least one first sterol and/or the at least one second sterol is capable of forming a complex with at least one first saponin and/or at least one second saponin, and ii) at least one first saponin and/or at least one second saponin, wherein the at least one second saponin is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and wherein the at least one first saponin and/or the at least one second saponin is capable of forming a complex with at least one first sterol and/or at least one second sterol, and optionally iii) at least one contacting group for contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, with the proviso that the at least one contacting group is present when no second sterol is present in the complex.

Foldvari et al. do not specifically disclose the use of a hydrocolloid adhesive or that one of the two compartments comprises a lyophilized pad comprising the immunogen and the other compartment comprises water or other appropriate solvent/diluent.

British Pharmacopoeia 1993 discloses wound dressings and medicated bandages, which include a semipermeable hydrocolloid dressing (see page 1943).

Foldvari et al. and British Pharmacopoeia 1993 disclose analogous inventions related to a product for transdermal delivery. It would have been obvious at the time the invention was made to use the hydrocolloid dressing of British Pharmacopoeia 1993 because it is a sterile, self-adhesive, waterproof, multi-component structure that would be effective in delivering at least one immunogen to an individual. Moreover, it would have been obvious at the time the invention was made to use the hydrocolloid because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Further, it would have been obvious to modify the compartments disclosed in Foldvari et al. to have the first compartment comprise a lyophilized pad comprising the immunogen and a second compartment comprise water or other appropriate solvent/diluent to help with preservation of the immunogen, inhibit the action of microorganisms and enzymes that would normally spoil or degrade the substance, to increase the shelf life and to quickly and easily rehydrate or reconstitute.

It would have been expected, barring evidence to the contrary, that the hydrocolloid dressing would be effective for transdermal delivery of at least one immunogen. KSR forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obvious. See the recent Board decision *Ex parte Smith,--USPQ2d--,* slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396).

By all comparative data the composition of the prior art and the instantly claimed composition absent evidence to the contrary are one in the same.

6. Claims 1, 2, 4, 5, 7-9, 10, 13, 16-27, 32-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Foldvari et al. (WO 99/11247) and Lee et al. (International Journal of Pharmaceutics, 2001; 221: 1-22).

The rejected claims are drawn to a Construct for transdermal delivery of at least one immunogen to an individual comprising:

a) said at least one immunogen;

b) an occlusion vehicle and

c) an immunogen delivery system;

wherein the immunogen delivery system is a complex comprising: i) at least one first sterol and/or at least one second sterol, wherein the at least one second sterol is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and wherein the at least one first sterol and/or the at least one second sterol is capable of forming a complex with at

least one first saponin and/or at least one second saponin, and ii) at least one first saponin and/or at least one second saponin, wherein the at least one second saponin is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and wherein the at least one first saponin and/or the at least one second saponin is capable of forming a complex with at least one first sterol and/or at least one second sterol, and optionally iii) at least one contacting group for contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, with the proviso that the at least one contacting group is present when no second sterol is present in the complex and further optionally iv) at least one lipophilic moiety.

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Foldvari et al. disclose that the membrane is designed to be a rate controlling membrane (see page 14, line 24).

Moreover, in addition to the vesicle-forming lipid component, the invention can include other lipid components capable of being incorporated into lipid bilayers, which for example can include sterols and saponin (see page 8, lines 17-19 and 21; page 12, line 6). Foldvari et al. disclose that the adhesive layer that sticks to the skin is made from a pharmaceutically acceptable pressure sensitive adhesive (see page 13, lines 12-14). Foldvari et al. disclose that a wide variety of immunogens are suitable for use in the present invention, which include but are not limited to antigens derived from microorganisms, such as a virus, bacteria, parasite and/or fungus (see page 6, lines 27-33 and page 7, lines 1-20). Lastly, Foldvari et al. discloses that the biphasic lipid vesicles of the invention include in the central core compartment of the lipid vesicle and in the aqueous space separating the lipid bilayers, an oil-in-water emulsion (see page 7, lines 23-25).

The product of the Foldvari et al. are the same as the instantly claimed invention, the product of Foldvari et al. necessarily i) at least one first sterol and/or at least one second sterol, wherein the at least one second sterol is capable of contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and wherein the at least one first sterol and/or the at least one second sterol is capable of forming a complex with at least one first saponin and/or at least one second saponin, and ii) at least one first saponin and/or at least one second saponin, wherein the at least one second saponin is capable of

contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, and wherein the at least one first saponin and/or the at least one second saponin is capable of forming a complex with at least one first sterol and/or at least one second sterol, and optionally iii) at least one contacting group for contacting a genetic determinant by means of an interaction selected from an electrostatic interaction and a hydrophobic interaction, with the proviso that the at least one contacting group is present when no second sterol is present in the complex.

Foldvari et al. do not specifically disclose the use of a hydrogel adhesive, cross-linked or otherwise, nor do they disclose that one of the two compartments comprises a lyophilized pad comprising the immunogen and the other compartment comprises water or other appropriate solvent/diluent.

Lee et al. disclose that hydrogels have been widely used as a drug carrier (see page 10; section 3.5)

Foldvari et al. and Lee et al. disclose analogous inventions related to a product for transdermal delivery. It would have been obvious at the time the invention was made to use a hydrogel because of its ease in manufacturing and self application (see Lee et al. Page 10). Moreover, it would have been obvious at the time the invention was made to use the cross-linked hydrogel because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the

combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Further, it would have been obvious to modify the compartments disclosed in Foldvari et al. to have the first compartment comprise a lyophilized pad comprising the immunogen and a second compartment comprise water or other appropriate solvent/diluent to help with preservation of the immunogen, inhibit the action of microorganisms and enzymes that would normally spoil or degrade the substance, to increase the shelf life and to quickly and easily rehydrate or reconstitute.

It would have been expected, barring evidence to the contrary, that the hydrogel would be effective for transdermal delivery of at least one immunogen. KSR forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obvious. See the recent Board decision *Ex parte Smith,--USPQ2d--*, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396).

By all comparative data the composition of the prior art and the instantly claimed composition absent evidence to the contrary are one in the same.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
9/25/08

/Robert A. Zeman/

for Lakia J. Tongue, Examiner of Art Unit 1645